CHANGE OF GRANTEE INSTITUTION

NAME: EMMONS, KAREN M
APPL NO:1 R03 CA50108-01
DUAL:
IRG:CCG(NIR)
FORMERLY: 1 R03 CA48437-01

COUN DATE: 05/8
RCVD:09-09-8

GRANT APPLICATION

Multiple Measures of Reducing Passive Smoke Exposure in the Workplace

X

"Cancer Prevention and Control Research Small Grant Program" 87-CA-37

Emmons, Karen Maria

Ph.D.

Assistant Professor of Clinical Psychology

Dept. of Psychiatry and Behavioral Medicine

University of Illinois College of Medicine
1 Illini Drive
Dept. of Psychiatry and Behavioral Medicine
Peoria, IL 61605

None

(309)671-8222

x

x

10/21/87 Brown/
Miriam Hosp.
M1095 Pending, UofI

9/30/88
9/29/89

$ 21,901

$ 34,385

$ 21,901

$34,385

University of Illinois College of Medicine
1 Illini Drive
Dept. of Psychiatry and Behavioral Medicine
Peoria, IL 61605

at Peoria

University of Illinois College of Medicine
Dept. of Psychiatry and Behavioral Medicine
1 Illini Drive
Peoria, IL 61605

Congressional District #18

x

x State

1-376-000511-A5

Profit General

Small Business

0 I

College of Medicine

BUSINESS OFFICE TO BE NOTIFIED BY PHS/ADAMHA Name title address

Mr. John P. Ward
Associate Director of Business Affairs
University of Illinois at Chicago
Box 6998, Chicago, IL 60680

Dr. Karen Hitchcock
Vice Chancellor for Research
University of Illinois at Chicago
Box 6998, Chicago, IL 60580

PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR ASSURANCE: I agree to accept responsibility for the scientific conduct of the project and to provide the required progress reports if a grant is awarded as a result of this application. Willful provision of false information is a criminal offense. US Code Title 18 Section 1001.

SIGNATURE OF PERSON NAMED IN 16a (Per signature for accredited above)

DATE

8/25/88

CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true and complete to the best of my knowledge and accept the obligation to comply with Public Health Service terms and conditions if a grant is awarded as the result of this application. Willful provision of false information is a criminal offense. US Code Title 18 Section 1001.

SIGNATURE OF PERSON NAMED IN 16a (Per signature for accredited above)

Karen K. Hitchcock

DATE

8/31

PHS 398 Page 3/85

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no pg 2

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Number of publications and manuscripts (*Not to exceed ten*) 4

*Other items (list):*

Letters [illegible]eport/contracts to our laboratory
Questionnaire Materials

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CHANGE OF GRANTEE INSTITUTION

Karen M. Emmons

~~DETAILED BUDGET FOR~~ FIRST 12-MONTH BUDGET PERIOD

DIRECT COSTS ONLY

9/30/88 9/29/89

| NAME | | | | |
|---|---|---|---|---|
| Karen M. Emmons, Ph.D. | | 1.0 | 50 | .30 |
| David B. Abrams, Ph.D. | Co-PI | 1.0 | 10 | .05 |
| TBN | Research Specialist | 0 | 100 | .25 |
| TBN | Graduate Student | .5 | 50 | .25 |

REDACTED

TOTAL REDACTED

CONSULTANT COSTS

Jack McCarthy, Sc.D. No Charge -0-

EQUIPMENT (Itemize)

-0-

SUPPLIES (Itemize by category)

Saliva containers, labels, packing materials ($100)
Spirometric supplies (disposable mouthpieces, antiseptic solution, calibration gauge) ($250)
Office Supplies ($ 50)

400

TRAVEL DOMESTIC -0-
FOREIGN -0-

PATIENT CARE COSTS INPATIENT -0-
OUTPATIENT -0-

ALTERATIONS AND RENOVATIONS (Itemize)

-0-

CONSORTIUM CONTRACTUAL COSTS

-0-

OTHER EXPENSES (Itemize by category)

saliva cotinine analyses 180 @ $15 each = $2,700
passive sampling analyses 180 @ $30 each = $5,400
active sampling analyses 90 @ $55 each = $5,400
standing environmental samples 12 @ $100 each = $1,200
mainframe computer time $200
postal costs $100

$15,000

TOTAL DIRECT COSTS FOR FIRST 12-MONTH BUDGET PERIOD (Item 7a) → $ 21,901

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*Number pages consecutively at the bottom throughout the application. Do not use suffixes such as 5a, 5b.

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Karen M. Emmons

BUDGET FOR ENTIRE PROPOSED PROJECT PERIOD
DIRECT COSTS ONLY

| BUDGET CATEGORY TOTALS | BUDGET FOR [1st] YEAR | ADDITIONAL YEARS OF SUPPORT REQUESTED |
|---|---|---|
| [illegible] SALARY AND WAGES [illegible] | $ REDACTED | |
| | -0- | |
| EQUIPMENT | -0- | |
| SUPPLIES | 400 | |
| TRAVEL [illegible] | -0- | |
| [illegible] | -0- | |
| PATIENT CARE COSTS [illegible] | -0- | |
| [illegible] | -0- | |
| ALTERATIONS AND RENOVATIONS | -0- | |
| CONSORTIUM/ CONTRACTUAL COSTS | -0- | |
| OTHER EXPENSES | 15,000 | |
| TOTAL DIRECT COSTS | 21,901 | |

TOTAL DIRECT COSTS FOR ENTIRE PROPOSED PROJECT PERIOD *Item 8a)* ⟶ $21,901

JUSTIFICATION Use separate sheet(s) if necessary. Describe the specific functions of the personnel, consultants, and other significant expenditures, such as major equipment, core or major alterations and renovations, consortium/contractual costs, other items as appropriate. For additional years of support requested, justify any significant increases in any category over the previous budget period. Justify significant increases with asterisks against the appropriate amounts. Explain any unusual increase in personnel costs and indicate the percentage. In addition, for COMPETING CONTINUATION applications justify any significant differences over the current level of support.

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BUDGET JUSTIFICATION

Personnel: The PI will assume responsibility for the scientific integrity of the project and the day to day operations. Salaries of PI and Co-PI are covered by other resources, 50% time and effort are denoted to this project. A 40% time research assistant is required to help the investigator implement the study protocol. The research assistant's responsibilities include: (a) preparing questionnaire and assessment materials (b) contacting potential subjects who respond to advertisements, and explaining the study protocol (c) scheduling appointments for self-monitoring training sessions, collection, and follow-up visits (d) training subjects in self-monitoring (e) collecting saliva samples (f) preparing data for analysis (coding, data entry).

Consumable Supplies: Saliva cotinine analysis will be conducted at the American Health Foundation, Valhalla, NY, under the direction of Dr. Nancy Haley. The discounted cost to the Miriam Hospital (because of the number of grants at the Miriam Hospital contracting with Dr. Haley's lab) is $15 per analysis. A total of 124 samples are required, because each person will be sampled once prior to, and following the smoking ban. Analysis of all monitoring devices will be provided by the Harvard/EPRI laboratory. This lab has offered all supplies and analysis to the Miriam Hospital at reduced cost because of the volume of samples needed, and because of the collaborative relationship that has been established. The combined cost of the passive filters and analysis is $30. The active monitoring will cost $55, and the standard air quality assessment will cost $100 per unit.

Publication Costs: Funds are required to offset the costs of publication, required by some professional journals.

Computer Time: Computer time on the Brown University mainframe IBM 370 will be needed to manage and analyze data, using SPSS-X and BMDP statistical software.

Miscellaneous Word Processing Supplies: These supplies are needed to offset paper and computer diskette costs.

Postal Costs: Saliva samples will be mailed to the American Health Foundation Lab for analysis in special containers needed to maintain their frozen condition.

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PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR Karen M. Emmons, M.A.

## BIOGRAPHICAL SKETCH

Give the following information for the key personnel and consultants listed on page 2. Begin with the Principal Investigator/Program Director. Photocopy this page for each person.

| NAME | POSITION TITLE | BIRTHDATE (Mo. Da. Yr.) |
|---|---|---|
| Karen M. Emmons, M.A. | Clinical Psychology Intern | R |

EDUCATION (Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)

| INSTITUTION AND LOCATION | DEGREE | YEAR CONFERRED | FIELD OF STUDY |
|---|---|---|---|
| State University of New York at Stony Brook | Ph.D. | 1988 | Clinical Psychology |
| State University of New York at Stony Brook | M.A. | 1986 | Clinical Psychology |
| University of Illinois | B.A. | 1982 | Psychology |

RESEARCH AND PROFESSIONAL EXPERIENCE: Concluding with present position, list in chronological order, previous employment experience and honors. Include present membership on any Federal Government public advisory committee. List, in chronological order, the titles and complete references to all publications during the past three years and to representative earlier publications pertinent to this application. DO NOT EXCEED TWO PAGES.

### RESEARCH AND PROFESSIONAL EXPERIENCE:

| | |
|---|---|
| 1987 - 1990 | Consultant, NIH grant. Oxone effect on respiratory tract mucus and permeability. (W.M. Foster, PI, SUNY at Stony Brook). |
| 1987 - 1988 | Project Director, CDC grant. Rhode Island workplace smoking reduction program (David Abrams, PI, Brown University). |
| 1986 - 1987 | Project Director, NIDA grant. The role of spouses in relapse prevention for smokers (R. Lorraine Collins, PI, SUNY at Stony Brook). |
| 1985 - 1986 | Project Coordinator, American Lung Association Grant, Nassau-Suffolk (NY) Chapter, The comparative efficacy of broad spectrum and relapse prevention approaches to smoking cessation. |

### GRANTS:

| | |
|---|---|
| 1987 | American Lung Association. The implications of pulmonary feedback in the prevention of smoking cessaion relapse. (Co-PI) Pending. |
| 1985 | American Lung Association. The comparative efficacy of broad spectrum and relapse prevention approaches to smoking cessation. (Co-PI) One-year funding. |

### PUBLICATIONS:

Emmons, K.M. & Weidner, G. (1987). The effects of cognitive and physical stress on cardiovascular reactivity among smokers and oral contraceptive users. Psychophysiology, in press.

### MANUSCRIPTS UNDER REVIEW:

Emmons, K.M. & Foster, W.M. The effect of smoking cessation on pulmonary responsivity to ozone.

Emmons, K.M., Weidner, G., Foster, W.M. & Colins, R.L. Improvement in lung function following smoking cessation: Implications for relapse prevention.

Emmons, K.M., Weidner, G. & Collins, R.L. Cardiovascular reactivity to stress and smoking cessation.

Emmons, K.M., Emont, S., Collins, R.L., and Weidner, G. The comparative efficacy of broad spectrum and relapse prevention approaches to smoking cessation.

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PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR Karen M. Emmons, M.A.

## BIOGRAPHICAL SKETCH

Give the following information for the key personnel and consultants listed on page 2 Begin with the Principal Investigator/Program Director Photocopy this page for each person.

| NAME | POSITION TITLE | BIRTHDATE (Mo., Day, Yr.) |
|---|---|---|
| David B. Abrams, Ph.D. | Co-Principal Investigator | R |

EDUCATION (Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)

| INSTITUTION AND LOCATION | DEGREE | YEAR CONFERRED | FIELD OF STUDY |
|---|---|---|---|
| University of Witwatersrand, South Africa | B.Sc(hons) | 1974 | Psych & Computer Sci |
| Rutgers University, New Jersey | M.S. | 1978 | Clinical Psychology |
| Rutgers University, New Jersey | Ph.D. | 1981 | Clinical Psychology |

RESEARCH AND PROFESSIONAL EXPERIENCE Concluding with present position list, in chronological order, previous employment experience and honors Include present membership on any Federal Government public advisory committee List, in chronological order, the titles and complete references to all publications during the past three years and to representative earlier publications pertinent to this application DO NOT EXCEED TWO PAGES

### RELEVANT PROFESSIONAL EXPERIENCE, ACADEMIC AND HOSPITAL APPOINTMENTS:

| | |
|---|---|
| 1979 - Present | Director of Research, Miriam Hospital, Division of Behavioral Medicine. |
| 1984 - present | Associate Director, Miriam Hospital Center for Health Promotion. |
| 1982 - present | Chairperson, Primary Prevention of Addictive Disorders Committee. Brown University Center for Alcohol Studies. |
| 1983 - present | Assistant Professor of Psychiatry and Human Behavior, Brown University Medical School. |
| 1986 | Study Section, NCI (Ad Hoc Technical Review Group). Heavy Smoker Community Trail. |
| 1986 | Consensus Panel: NHLBI. Relapse Prevention. National Institutes of Health, Bethesda, MD. |
| 1986 | *Site Visitor:* NCI, Study Section for Program Project Applications (Center Grants). Heavy Smokers Trial. Division of Cancer Control. National Institutes of Health, Bethesda, MD. |
| 1986 | Consensus Panel: NCI. Standards for Biochemical Evaluation of Smoking Prevalence. NIH, San Francisco, CA. |
| 1987 | Consensus Panel: NHLBI. Smoking policy at the workplace. The Lung Branch, National Institutes of Health, Bethesda, MD. |
| 1987 - 1988 | Consensus Panel: NAS, *Institute of Medicine, Division of Health Sciences Policy.* Prevention and treatment of alcohol-related problems: An update on research opportunities. National Academy of Sciences, Washington, DC. |
| 1987 | Study Section: NIAAA. Treatment Research Group. Bethesda, MD. |

### RELEVANT PAPERS AND PUBLICATIONS: (Selected out of 53).


Abrams, D.B., et al. (1986). A comprehensive framework for conceptualizing and planning organizational health promotion programs. Chapter in M. Cataldo & T. Coates (eds.), Behavioral Medicine in Industry, John Wiley.

Lichtenstein, E., Glasgow, R., & Abrams, D.B. (1986). Social support in smoking cessation: In search of effective interventions. Behavior Therapy, 17, 607-619.

Abrams, D.B., Follick, M.J., Biener, L., & Carey, K.B. (1987). Saliva cotinine as a measure of smoking status in field settings. American Journal of Public Health, 77(7), 846-848.

Abrams, D.B., Monti, P.M., et al. (1987). Psychosocial stress and coping in smokers who relapse or quit. Health Psychology, 6(4), 289-303.

Pinto, R., Abrams, D.B., et al. (1987). Nicotine dependence and likelihood of quitting smoking. Addictive Behaviors, 12, 371-374.

Carey, K.B., Abrams, D.B. (1987). Properties of saliva cotinine in light smokers. American Journal of Public Health, in press.


### RESEARCH GRANTS: (SEE OTHER SUPPORT)

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PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR: Karen M. Simmons, M.A.

## BIOGRAPHICAL SKETCH

Give the following information for the key personnel and consultants listed on page 2. Begin with the Principal Investigator/Program Director. Photocopy this page for each person.

| NAME | POSITION TITLE | BIRTHDATE (Mo., Day, Yr.) |
|---|---|---|
| John Francis McCarthy | Consultant | R |

EDUCATION (Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)

| INSTITUTION AND LOCATION | DEGREE | YEAR CONFERRED | FIELD OF STUDY |
|---|---|---|---|
| Boston College | B.S. | 1973 | Biology |
| Harvard University | M.S. | 1978 | Environmental Healt |
| Harvard University | Sc.D. | 1987 | Environmental Scienc and Physiology |

RESEARCH AND PROFESSIONAL EXPERIENCE: Concluding with present position, list, in chronological order, previous employment, experience and honors. Include present membership on any Federal Government public advisory committee. List, in chronological order, the titles and complete references to all publications during the past three years and to representative earlier publications pertinent to this application. DO NOT EXCEED TWO PAGES.

### PROFESSIONAL EXPERIENCE:

1980 - Present — Research Scientist, Director, Aerosol Characterization Laboratory. Energy Laboratory Massachusetts Institute of Technology, Cambridge, MA.

1978 - 1980 — Research Scientist. Energy Laboratory, Massachusetts Institute of Technology, Cambridge, MA.

### RELEVANT PUBLICATIONS:


Amdur, M.O., McCarthy, J.F., and Gill, M.W. Effect of mixing conditions on irritant potency of zinc oxide and suflur dioxide. American Industrial Hygiene Association Journal, 44(1), 7-13, 1983.

Neville, M., McCarthy, J.F., and Sarofim, A.F. Processing of submicron coal combustion aerosols for chemical analysis. Atmospheric Environment, 17, 2599-2604, 1984.

Amdur, M.O., Sarofim, A.F., Neville, M., Quann, R., McCarthy, J.F., Elliott, J.F., Lam, H.F., Rogers, A.E., and Connor, M.W. Coal combustion aerosols and SO2: An interdisciplinary analysis. Environmental Science and Technology, 20(2), 138-145, 1986.

McCarthy, J.F., and Spengler, J.D. Assessing exposure to environmental tobacco smoke. Chapter 3 in "The Health Consequences of Smoking: Involuntary Smoking." Report of the Surgeon General: 1986, US Department of Health Education and Welfare, Public Health Service.

Lebret, E., McCarthy, J.F., and Spengler, J.D. Exposure assessment in air pollution epidemiology. To appear in the Proceedings of the APCA Specialty Conference on Environmental Risk Management, April 8, 1986, Chicago, Ill.

McCarthy, J.F., Mohiuddin, G., and Neville, M. Detection of sulfuric acid aerosols by a mobility classifier system. Submitted to Journal of the Air Pollution Control Association, September, 1987.

McCarthy, J.F., and Peoples, S.M. X-ray photoelectron spectroscopy studies of submicrometer copper oxide participles. Submitted to Atmospheric Environment, September, 1987.


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# OTHER SUPPORT

*(Use continuation pages if necessary)*

*FOLLOW INSTRUCTIONS CAREFULLY Incomplete, inaccurate, or ambiguous information about OTHER SUPPORT could lead to delays in the review of the application. If there are changes subsequent to submission notify the executive secretary of the initial review group*

For each of the key personnel named on page 2 list, in three separate groups: (1) *all* currently active support; (2) *all* applications and proposals pending review or funding, and (3) applications and proposals planned or being prepared for submission. Include *all* Federal, non-Federal, and institutional research, training, and other grant, contract, and fellowship support at the applicant organization and elsewhere. If part of a larger project, identify the principal investigator/program director and provide the data for both the parent project and the subproject. If none, state "none."

For each item give (a) the source of support, identifying number and title, (b) percentage of appointment on the project; (c) dates of entire project period; (d) annual direct costs; (e) a brief description of the project, (f) whether the item overlaps, duplicates, or is being replaced or supplemented by the present application; delineate and justify the nature and extent of any scientific and/or budgetary overlaps or boundaries, and (g) any modifications that will be made should the present application be funded.

PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR Karen M. Emmons, M.A.

(1) CURRENTLY ACTIVE SUPPORT. (a): None

(2) Pending Funding: ALA Grant funded ~.01 effort

(3) Applications planned for submission: None

Co-Principal Investigator: David B. Abrams, Ph.D.

(1i) Current Active Support:

(a) Psychosocial Stress, Smoking and CHD. National Heart, Lung, and Blood Institute, Grant #5 RO1 HL 32318;
(b) Twenty Percent Time, Principal Investigator
(c) 9/30/83 - 9/29/89
(d) $142,874, annual direct costs.
(e) Study individual differences in cardiovascular reactivity to stress and smoking cues as predictors of early relapse in smokers. Develop new treatments for relapse prevention based on an exposure-coping skills social learning model of relapse.
(f) There is essentially no overlap except in conceptual issues and measurement instruments (questionnaires).
(g) No modifications planned.

(1ii) (a) Self-help smoking cessation at the workplace. National Cancer Institute Grant # 5 RO1 CA 38309.
(b) Thirty-five Percent Time and effort, Principal Investigator.
(c) 9/30/84 - 8/31/89
(d) $227,586, annual direct costs.
(e) Evaluation of individual, group, and organizational levels of intervention to optimize reductions in smoking prevalance at the workplace, using low-cost, self-help techniques.
(f) No overlpa.
(g) No modifications planned.

See Continuation

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(2) Pending Funding. None

(3) Applications planned: None.

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## RESOURCES AND ENVIRONMENT

FACILITIES: Mark the facilities to be used at the applicant organization and briefly indicate their capabilities. Describe only relevant resources. Use continuation pages if necessary. Include an explanation of any consortium/contractual arrangements with other organizations.

☐ Laboratory

☐ Clinical

☐ Animal

☒ Computer

The computer facilities of Brown University will be used for major data evaluation efforts. The project will have access to a portable terminal that can be connected to the Brown system using a telephone line. The facilities and the staff of the Brown University Computer Center are very experienced in the storage, maintenance, and processing of large data sets. Brown has an IBM 370-158 for interactive usage and a 370-148 for batch processing. The 370-158 has peripheral equipment consisting of 7-track and 9-track tape drives for 800 to 6250 BPI, card read/punch units, and three high-speed printers. The operating systems available are OS/MVT and OS/VSI, with CMS time-sharing operating system. The stability of the system is excellent. The remote terminal will enable our Staff to generate OS-370 jobs and submit those jobs for OS/370 batch processing. The Brown University Computing Center has available many software packages, including SPSS-X, SAS, and BMDP.

☐ Office

☒ Other (Specify)

The Harvard/EPRI laboratory has agreed to fully participate in the implementation of this project. Dr. McCarthy, our consultant, has arranged for a graduate student of his to be available throughout data collection. This individual's role will be to maintain all environmental monitoring equipment. In addition, the Harvard/CPRI laboratory will analyze all environmental monitoring samples. The American Health Foundation Laboratory (Valhalla, NY) will analyze frozen saliva samples. Dr. Nancy Haley will conduct the analysis. A written contract has been made, and is available upon request.

MAJOR EQUIPMENT: List the most important equipment items already available for this project. Indicate location and pertinent capabilities.

- Portable, computerized spirometer (Fukada-Sangyo Model ST-200).
- A -70° freezer is available for storing saliva samples for subsequent cotinine analysis.
- Portable, active sampling pumps for measurement of respirable particulate matter.
- Standing air quality sampling monitors.

ADDITIONAL INFORMATION: Provide any other information describing the environment for the project. Identify support services such as consultant, secretaries, machine shop, and electronics shop and the extent to which they will be available to the project.

Basic office space and facilities are available within the existing facilities of The Miriam Hospital. The Division of Behavioral Medicine at The Miriam Hospital has been conducting research in the area of smoking cessation for over 6 years. The project directors and support staff of the existing projects will be available for informal consultation. Members of the data management team in the Smoking Research Laboratory will provide computer-based data management.

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## Specific Aims

Despite their enormous potential as a vehicle for policy, community, organizational and individual change efforts, few studies have been conducted on passive smoke exposure among non-smokers. Recent advances in measurement technology now make exploration of this question possible. This project has been designed to evaluate several aspects of measuring changes in passive smoke exposure in the workplace. These aspects have direct relevance for designing interventions to reduce smoking behavior. Specific goals are:

(1) to develop and validate non-invasive methodologies for detecting low levels of smoke exposure found in non-smokers;

(2) to evaluate the comparative sensitivity and specificity of these methodologies;

(3) to evaluate the impact of a worksite smoking policy restriction/ban on the total passive smoke exposure of non-smokers;

(4) to determine the impact of a worksite smoking ban on other measures of health among non-smokers specifically pulmonary function.

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Significance

Passive smoking has been identified as a risk factor for lung cancer and chronic obstructive pulmonary disease among healthy non-smokers (1,2,3,4,5,6,7). Exposure to passive smoke increases acute respiratory symptoms and leads to a decrement in pulmonary function (8,9,10,11,12). Field surveys investigating non-smokers' exposure to tobacco smoke across a variety of settings have found that the average exposure of non-smokers to tar from cigarettes is 1.43 mg per day (range = 0 - 14 mg/day) (15,16). Probability of passive smoke exposure across all environments was found to be 86%.

It has been demonstrated and replicated that low levels of cotinine, the major metabolite of nicotine, can be measured, for example, among children of smoking parents by analysis of cotinine in blood, urine, or saliva (13,14). However, there has been little investigation of the measurement of saliva cotinine, the least invasive procedure, among non-smoking adults and almost no research that we know of in the workplace. Approximately 80% of total passive smoke exposure is estimated to originate from the workplace (17). Thus, for most non-smokers, the majority of their passive smoke exposure occurs at their place of employment.

Policies limiting smoking in the worksite have become increasingly widespread and restrictive. However, less than 40% of worksites surveyed have been found to have any type of smoking policy (18,7). Despite strong employee support for smoking restrictions (19,20), fear of worker discontent is the most frequently cited reason for failure to adopt worksite smoking policies. In addition, the direct health benefit to non-smokers resulting from restrictive smoking policies has not been firmly established. Further, it is not clear if the current methods of detecting passive smoke exposure are sensitive enough to reflect reduced exposure that would result from restrictive smoking policies. Thus, from the perspective of employers whose policy decisions would be primarily motivated by reduced health care utilization, there may be minimal motivation for adopting smoking policies at the present time.

With increasing concern about risks of passive smoking it is important to intervene not only at the policy level within worksites but at other group and individual levels as well, in order to maximize social influence mechanisms. It has been suggested (21) that organizational level interventions (such as worksite policy change, competition, and goal setting with feedback on group performance), in combination with individual level interventions (such as individual social pressure from non-smokers, and low-cost self-help smoking cessation programs) can act synergistically to promote cessation and reduction of smoking in the workplace. System level and individual level interventions

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targeted at measuring and reducing passive smoke exposure in non-smokers could also improve the effectiveness of the workplace as an agent of both health promotion and disease reduction by increasing social and organizational pressures to reduce smoking. Development of a comprehensive, cost-effective and disseminable approach to smoking reduction in the workplace would contribute significantly to the reduction of passive smoke exposure as well as to the reduction and prevention of cancer among both smokers and non-smokers.

A crucial component of an organizational systems approach is to increase social pressure to change or reduce smoking through policy change. This must be done in a socially responsible manner to prevent a boomerang effect from smokers. Implementation of a smoking ban, for example, could result in the reduction of passive smoke exposure by 33-100% (18). However, unless evidence can be provided to employers and employees documenting the health impact of reduced passive smoke exposure, it is unlikely that substantial changes in either individual attitudes and/or worksite policies will occur. It would be of major significance to add this data about passive smoke exposure to enhance the power of comprehensive worksite smoking reduction programs as part of the development of large-scale nation-wide workplace smoking reduction/health promotion campaigns.

Preliminary Studies

The PI, Karen Emmons, is a Ph.D. candidate in Clinical Psychology at SUNY-Stony Brook. She has completed and successfully defended her dissertation work and will receive her degree in August, 1988, following completion of her internship at Brown University Medical School/The Miriam Hospital. At that time, it is anticipated that she will be joining the Smoking Cessation Research Group on a full-time basis.

The PI has planned and implemented a number of research projects involving smoking cessation (22,23,24,25,26). Most relevant to the present proposal is research investigating the impact of smoking cessation on pulmonary responsivity to ozone, an environmental stressor (25). Unlike healthy non-smokers who have a reduction in pulmonary function upon exposure to ozone, smokers have virtually no pulmonary reactivity to ozone (27). However, in this study it was demonstrated that, following 6 months of smoking cessation, there was a significant reduction in pulmonary function in response to ozone exposure . This study suggests that pulmonary responsivity to certain environmental irritants does return to normal after smoking cessation.

The PI is currently serving as Project Director on a project funded by the Center for Disease Control/Rhode Island Department of Health to determine the impact of providing non-smokers with feedback about their passive smoke

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exposure level on their subsequent exposure levels. The goal is to determine if feedback will induce a behavior change such that non-smokers will reduce their exposure to passive smoke. We are presently in the process of recruiting worksites for this project, and are piloting self-monitoring materials that will be used to provide a subjective estimate of exposure. The present proposal focuses on a set of different questions and uses different multiple measures. This proposal does draw upon the CDC ideas, although there is no overlap between the two projects with respect to funding. The advantage of the CDC/RIDH contract is that it allows us to develop and validate several components of this proposal that would not be possible given the present budget and time restrictions. For example, the self-monitoring materials developed and validated as part of the CDC/RIDH project will be used in the proposed study. A spirometer and computers for data entry are also available (see "Resources and Environment") to us from this project.

Ongoing work, directed by the Co-PI - Dr. Abrams, is also related to the present study. Dr. Abrams is also a PI on a 5-year worksite-based smoking cessation study utilizing a self-help treatment protocol (NCI grant # 38309, $1.2 million). This study is currently in its 4th year of funding. In addition, a 4-year project was recently completed which evaluated the role played by psychosocial stress variables in smoking cessation at the worksite (NHLBI grant #32318, $480,000). This study was renewed via competitive continuation and will be ongoing for another 3 years until 1989. These studies illustrate the ability of the PI and Co-PI to conduct smoking research in the worksite setting. This smoking research group at Brown University/Miriam Hospital has published a number of studies demonstrating the feasibility of saliva continine collection in field trails. As part of the self-help smoking cessation intervention at the workplace, Abrams et al., (28) determined that saliva cotinine is a reliable and sensitive measure of change in smoking rate among smokers who reduce and/or quit smoking. We have also examined the properties of saliva cotinine in light smokers (29) indicating that as little as one cigarette smoked in the prior 24 hours will produce measurable elevations in saliva cotinine. Furthermore, studies of changes in self-reported smoking after policy change and a theoretical/conceptual paper that outlines ways to maximize the impact of individual and organizational components of a smoking cessation program have also been published or presented (see Appendix for reprints).

Thus, the present study adds an important component to our programmatic line of research on uncovering cost-effective methods to maximize smoking cessation/reduction at the workplace. The long-term goal resulting from the proposed study is to add to knowledge about what components are likely to be effective at influencing the adoption of more restrictive smoking policies in worksites, thereby accelerating cessation, reducing passive smoke exposure

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*and consequently* the health risks due to smoking. Providing employers and employees with empirical evidence that passive smoke exposure is detectable, and cen be reduced, may have a substantial impact on individual motivation and on public policy legislation.

One of the greatest challenges to a smoke-free society is to motivate the vast majority of smokers who are not yet taking action to quit. The use of sallva cotinine assessment in non-smokers could be an important component of accelerating the growing movement towards a smoke-free society, especially when it is combined with other strategies in a comprehensive community and organizational approach to smoking reduction/cessation. Furthermore, providing readily available individual tests of passive smoke exposure on a community-wide basis (rather than only at worksites) could motivate non-smokers to avoid smoking in all settings and encourage smokers who live in households with non-smokers to consider cessation.

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## Design

A 2 X 2, repeated measures design will be used to evaluate the impact of a smoking ban on the cotinine, nicotine, and respirable particulate (RSP) exposure of non-smokers (see Figure 1). The experimental and control settings employ a quasi-experimental design because it would be very expensive and impractical to use worksites as the unit of analysis for this type of preliminary study. Several replications across pairs of worksites might be possible but at least one in each condition (restriction or ban versus no restriction or ban) is needed.

Figure 1

| | | Time: Pre-Ban | Time: Post-Ban |
|---|---|---|---|
| Policy Condition | Ban | | |
| | No Ban (control) | | |

Pre-treatment measurements and an attempt to match pairs of worksites will be used to control for pretreatment differences to ensure that results can be interpreted as due to the indepedent variable and not other extraneous factors. This type of approach to design has been accepted and adopted by several research groups in the area of health promotion despite its obvious limitations.

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In an effort to develop a comprehensive yet cost-effective technology for the detection of passive smoke exposure, several assessment methods will be used. These include self-monitoring of exposure, active sampling of RSP and nicotine, and passive RSP and nicotine sampling. In addition to these measurements of passive smoke exposure, measurement of air quality, and ventilation, will be taken prior to and 6 months following implementation of a policy banning smoking in the experimental (Ban or restriction) worksite(s). Identical measures will be taken in the control worksite(s) to ensure that results found in the experimental group do not reflect changes in confounding factors such as a history effect due to changes in population social norms.

Rationale: There are biochemical markers available for the detection of nicotine and its metabolities in smokers (30,31,32), and some of these methods have been used for measurement of passive smoke exposure in non-smokers (33,34,35). Some preliminary work has been done to examine the relationship between biochemical markers and environmental measures of exposure in children (36). However, little work has been done with adults to evaluate the relationship between different measures of exposure. Since the environment and lifestyle patterns of adults are quite different from those of children, it cannot be assumed that relationships documented in children are generalizable to adults. The effect of a smoking ban in the worksite must be empirically determined before public health efforts to induce policy change individual and/or will be optimally effective. Technology must be identified that is sensitive to a reduction in passive smoke exposure. Therefore, the proposed repeated measures design will make it possible to evaluate the sensitivity to reductions in exposure of several techniques that assess passive smoke exposure. Further, this study will assess the direct health impact of exposure reductions as measured by pulmonary function. There is considerable evidence that passive smoke exposure is related to reduced pulmonary function (8,9,10,11). Thus, the present proposal will determine if reduced passive smoke exposure at the worksite is sufficient to promote improvement and/or recovery of lung function.

## Method

Subjects. Our laboratory is currently conducting worksite smoking interventions in six workplaces using the NCI funded grant (see Appendix A for copies of contracts), and an additional six sites are currently being recruited for the CDC/RIDH passive smoking grant. Thus, we have access to twelve worksites that are committed to the delivery of comprehensive smoking reduction programs, including the examination of smoking policy. It appears that over the next 2 years several of these worksites will modify their smoking policy or ban smoking. In addition, several buildings have been

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identified at Brown University that are known to be planning total smoking bans. Thus, we believe we can obtain at least one and perhaps more sites that will sufficiently restrict or ban smoking to make this study possible. Furthermore, we believe that the multiple measures of exposure data at pre-ban will yield extremely valuable information for future studies of this type. Subjects in the experimental group will be all non-smoking employees in one (or more) worksite(s) that is (are) planning a smoking ban, selected from the 12 worksites to which we have access. A control worksite will then be selected and matched for pre-intervention smoking policy. It should be noted that, based on our access to a large number of worksites, it may be quite feasible to replicate and extend the findings of this project to several pairs of worksites. Since all of the worksites employ more than 350 workers, we can easily attain our sample size of non-smokers (N = 45) from any one of them.

All subjects will be at least 19 years of age, and will have been continuously abstinent for a minimum of 1 year. Subjects who report smoking cigars, pipes, or marijuana or being exposed to other forms of smoke other than cigarettes will be excluded.

Procedure:

Meetings will be held with supervisory personnel and employees to generate support and enthusiasm for the study. Interested people will be screened by a very short questionnaire. Following screening, participants will meet in small groups during working hours to read and sign the consent form, and to fill out a questionnaire regarding their passive exposure to cigarette smoke. Participants will be trained in the self-monitoring procedure, and they will be asked to complete a daily diary of their smoking exposure for 1 week. Half of each group will be randomly selected to wear the passive RSP monitoring filter continuously during this period (Please see "Monitoring Devices" section for a complete description). This subsample will also wear the active sampling device during their work hours. In addition, small standing pump devices designed to measure air quality will be placed in the office areas of subjects in the latter subsample. At the end of the monitoring week, all subjects will provide a saliva sample. The sample will be deposited by the subject directly into a sterile vial labelled with the participant's code number and marked for a 2 ml. sample, following the procedures outlined in Abrams, et al. (28). In addition, subjects will complete a pulmonary function test on a portable spirometer (Fukada, Sangyo, Model-ST 200). The passive and active monitoring filters, and the air quality samples will be collected and analyzed by in the laboratory of McCarthy and Spengler at Harvard School of Public Health (see Appendix A for letter of agreement). This procedure will be followed in both the experimental and control worksites prior to and 6 months following implementation of a smoking ban in the experimental worksite.

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Setting. This study will be run in the context of pairs of worksites: one that is about to restrict smoking or implement a smoking ban, and one in which there will be no planned change during the study period. The sites will have been matched for their pre-test smoking policies and smoking prevalence. In addition, the sites will be matched, if possible, for type of ventilation systems in order to control for the impact of air re-circulation on exposure to particulate matter.

Monitoring Devices

Passive Sampling. The passive monitor will be worn by all subjects throughout the 1 week monitoring period. Subjects will be instructed to wear this device at all times, except when they are sleeping. The passive filter is small and can be worn in a rather inconspicious manner. The passive monitor will be analyzed for both nicotine, cadmium, and RSP. Preliminary data in the Harvard/EPRS Laboratory suggest that cadmium is more stable and long-lasting than nicotine. The passive monitor is constructed from a 37 mm diameter polystyrene air sampling cassette. An alligator clip is riveted to the bottom of the cassette so the monitor can be conveniently attached to clothing. A support pad and a glass fiber filter that has been saturated in an aqueous solution of 4% sodium bisilfate and 5% ethanol are placed in the bottom of the cassette. The sampling rate is 25 mL/min. A modified version of this monitor has been validated in an environmental chamber under controlled and field conditions (37), and validation studies on the present version of the monitor are underway and will be completed prior to the implementation of the proposed study.

Active Sampling. A subsample, derived from random selection of several office units, will carry personal monitors to collect both respirable suspended particulate matter (RSP) and nicotine for consecutive samples. The active sampling system has been well-validated in both the lab and the field (37, 38). The Harvard/EPRI personal monitoring pump that operates at 1.7 L/min. with a 10 mm nylon cyclone perseparator (38) will be placed in a small padded pack and carried over the shoulder. The cyclone will be clipped to the shoulder strap near the subject's breathing zone. Subjects will be asked to keep the monitor with them at all times during working hours. When possible, the units will be plugged into a wall socket and placed in close proximity to the subject. Otherwise, pumps will be powered by a 12V nickel-cadmium rechargeable battery with a lifetime of approximately 12-14 hours. Flow checks with a calibrated rotameter will be performed by project staff at the beginning and end of each sampling period. RSP samples will be collected on tared 37 mm Fluropore filters (Millipore Corp.) and reweighed on a Cahn 21 electrobalance. Nicotine form sidestream smoke is primarily in the vapor phase (39), and therefore it can be efficiently collected on a glass fiber backup filter treated

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with sodium bisulfate to minimize volatilization of nicotine vapor. The extraction procedure is a modification of that presented by Hammond, et al, (37). Since all non-smoking members of a particular office will be asked to wear the monitors, compliance is not anticipated to be a problem. However, pilot testing prior to full-scale data collection will be done to clarify this issue.

Indoor Sampling. The indoor control monitor is essentially the same design as the active monitor. However, since the indoor monitor assesses ambient air, rather than the individual breathing zone, it will be plugged into a wall socket in each office for the duration of the sampling period. The indoor monitor provides a measure of overall air quality.

Saliva Cotinine Analysis. Cotinine, a long-lived metabolite of nicotine, has been shown to be a reliable measure of tobacco smoke exposure, and has greater specificity in separating smokers from non-smokers than plasma and saliva thiocyanate or blood carboxyhemoglobin (30,32). Further, saliva cotinine has been found to discriminate between children who have low, moderate, and high levels of passive smoke exposure (33). Saliva cotinine will be quantified by radioimmunoassay (40). These analyses will be conducted at the American Health Foundation (Valhalla, NY). We may consider a more sensitive assay technique (200 picograms) recently reported that uses GLC (gas liquid chromatography), (Benowitz, personal communication) pending results from a study we are currently conducting to assess the validity and sensitivity of GLC in detecting passive smoke exposure.

Sample Size. Sample size estimation first requires an estimate of the expected magnitude of experimental effects. This estimate is based on the assumption that there will be no reduction in exposure in any environments other than work. Evidence suggests that approximately 80% of passive smoke exposure occurs at work, (17), and 20% at home or in other situations. However, a more conservative estimate of 60% exposure at the workplace will be used to reduce the probability of a type II error. Thus, it is anticipated that 40% of environmental smoke exposure will remain unchanged as a result of a total smoking ban. The expected reduction in cotinine exposure is equivalent to a 60% reduction, assuming that there is complete elimination of workplace exposure.

Data provided by Jarvis, et al., (33) documenting saliva cotinine levels of individuals with moderate passive smoke exposure was used to provide an estimate of the sample size for the present study.

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Calculation of the effect size (ES) adjusted for correlated samples yields:

$$ES = \frac{1.95 \text{ (moderate)} - .78 \text{ (60\% reduction)}}{2.25}$$
$$= 0.52\sqrt{2}$$
$$= .74$$

Using Cohen's (41) tables for sample size estimation (pp. 55) with alpha (2-tailed) set to .05 and power set to .90 (to reduce the risk of type II error), an ES of .74 yields an approximate sample size of 38 subjects per condition. Assuming a conservative 20% attrition rate due to non-compliance with the protocol and loss to follow-up, yields a total of 90 subjects (45 per condition). This sample size should be attainable from within any one of the worksites currently involved in our studies (sizes range from 350 to 1,500 employees).

Dependent Measures

Dependent Variable:

Passive Smoke Exposure

The following outcome measures will be utilized: (1) self-reported passive smoke exposure, based on 1 week of self-monitoring; (2) saliva cotinine levels; (3) nicotine exposure levels, determined by active and passive sampling; (4) cadmium levels, determined by passive sampling; (5) RSP levels determined by active sampling (6) air quality assessments, determined by indoor monitoring.

Pulmonary Function: At the end of the self-monitoring period subjects will be asked to complete a pulmonary function test. All measurements will be made on a computerized spirometer (Fukada-Sangyo, model ST-200) by the PI, who has received training in the spirometric measurement of pulmonary function. The Director of the Pulmonology Department, Dr. Daniel Ledderer, will provide consultation on this project, supervise administration of spirometry, and interpret the results (see Appendix A for letter of support). All maneuvers will be performed until two technically acceptable tracings are obtained. The tracing that yields the best measurement will be used for analysis. Forced expiratory volume at 1 second, forced vital capacity, and maximum midexpiratory flow will be calculated and compared to predicted normal values based on the subject's age, sex, and height (42). Following completion of the post-ban assessment, subjects will be provided with information, compared to normative standards, about both measurements of their lung function. In addition, copies of the results will be sent to subjects' personal physicians following provision of written consent by the subjects. The measurement of

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pulmonary function in this project is in accordance with the American Thoracic Society's recommendations for the screening of non-smokers (43).

Measures

Demographics and Attitudes about Smoking. This questionnaire (see Appendix B for a preliminary version) is based on pilot data from our laboratory. The questionnaire assesses a subjective estimate of passive smoke exposure, in addition to attitudes and beliefs regarding the health effects of passive smoking.

Data Analysis:

Chi-square analyses will be used to verify that there were no differences between conditions on pre-treatment gender. Repeated measures analysis of variance will be used to evaluate differences between and within the conditions in pre- and post-ban passive smoke exposure, as measured by self-monitoring, saliva cotinine analysis, active and passive monitoring of RSP and nicotine, and indoor air quality. Pearson correlational analyses and multiple regression analyses will be used to evaluate the relationship between the various methods of measuring passive smoke exposure. Spirometric data will be analyzed by repeated measures analysis of variance.

One potential confound will be the effect of varying levels of passive smoke exposure outside of the work environment. For example, more non-smokers in one of the policy conditions may live with smokers. In order to evaluate the influence of this potential confound, exposure in all environments will be documented via the self-monitoring diaries. In addition, the passive monitors will provide an assessment of overall exposure. If it appears that exposure in other settings is differential across experimental conditions, blocking based on outside of work levels of exposure may have to be utilized. This will be decided during pretest screening of subjects before the final samples are selected. Ideally, we may even want to select only those non-smokers who have smoke-free households (in both experimental and control settings) so as to ensure that most of their exposure is likely to originate from the workplace. This limits generalizability to some degree but is justifiable in an initial study where avoiding type I and II errors, and maximizing internal validity are paramount.

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## Timetable

The project is estimated to require 1 to 2 years to complete. Since much of the material has been developed and previously validated as part of our on-going research, little time is needed for start-up activities. In addition, we currently have access to worksites, so little time has been allocated for recruitment. It is estimated that all subjects can be trained in the self-monitoring procedure within approximately 2 weeks. Therefore, data collection will be staggered by 2 weeks for the 2 worksites.

| | |
|---|---|
| Months 1 - 2 | Prepare materials<br>Advertise for subjects (end of Month 2) |
| 3 | Respond to inquires from potential subjects<br>Schedule self-monitoring training sessions<br>Complete self-monitoring training sessions and collection of questionnaire data. |
| Restriction/Ban site: 1st 2 weeks<br>No Restriction/No Ban Site: 2nd 2 weeks | Subjects monitor for 1 week and wear filter<br>Saliva/filter samples are collected |
| 4 | Smoking Ban starts in experimental worksite |
| 5 - 9 | Data coding/entry<br>Analysis of pre-ban saliva, filters, and self-monitoring data<br>Recontact subjects for follow-up (end of Month 9) |
| 10 | |
| Restriction/Ban site: 1st 2 weeks<br>No Restriction/No Ban Site: 2nd 2 weeks | Subjects monitor for 1 week and wear filter<br>Saliva/filter samples are collected |
| 11 - 12 | Post-ban data coding, entry, and analysis<br>Preparation of manuscript for publication |

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## Human Subjects

E1. Subjects will be 90 adult males and females, age 19 or older, who are non-smokers. All subjects work in either the experimental or control worksites, and their participation is strictly voluntary. Subjects who report exposure to marijuana or other forms of smoke will be excluded. No exclusions will be made based on health status.

E2. Questionnaries, saliva samples, nicotine, cadmium, and RSP samples, and self-monitoring diaries will be obtained from each subject. All data will be collected for research purposes only, and will be stored in locked files with only code numbers identifying subjects. A master list will be kept separately to facilitate follow-up data collection. Only grant staff, with the permission of the PI, will have access to the master list linking names to code numbers.

E3. Subjects will be recruited by flyers/ads and payroll stuffers in the worksites. In addition, administrators will write letters to employees in support of the study, and meetings will be held with supervisors and employees to generate support and participation. Fully informed consent will be obtained at the self-monitoring training session. The program will be described at this meeting and during the previous telephone contact, and subjects will have an opportunity to ask the PI any questions. Two copies of the consent form will be given to each subject. One copy must be signed and returned to grant staff prior to the training session, and subjects may keep the other copy of the consent form for their own information. The Miriam Hospital Human Subjects Review Board and the RIDH Review Board have completed review of this protocol, and approval has been granted by both committees.

E4. - 5. Risks are minimal. There are no known risks involved in filling out the questionnaires or providing a saliva sample. Subjects may be slightly inconvenienced by filling out the daily diary for 7 days or by wearing the personal monitoring filter. Breech of confidentiality is highly unlikely given the numerical coding system.

E6. Benefits outweigh risks. Subjects may learn important information about their own exposure to passive smoke. In addition, at the conclusion of the study the results of each subjects' saliva and filter analyses and pulmonary function test results will be made available to him/her and spirometric results will be sent to the subject's physician .

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HARVARD UNIVERSITY
SCHOOL OF PUBLIC HEALTH

KRESGE CENTER FOR ENVIRONMENTAL HEALTH
DEPARTMENT OF ENVIRONMENTAL HEALTH SCIENCES

665 Huntington Avenue
Boston, Massachusetts 02115

December 6, 1987

Dr. Karen Emmons
Miriam Hospital
Department of Behavioral Medicine
164 Summit Avenue
Providence, RI 02906

Dear Karen:

As per our earlier conversation I would be pleased to participate as a consultant on your research project entitled "Multiple Measures of Passive Smoke Exposure in the Workplace". This is an extremely interesting project and will provide insight as to the true level of exposure in the workplace.

This information will also be useful as input in risk assessment calculations and for estimating total human exposure to environmental tobacco smoke.

I look forward to working with you on this project.

Sincerely,

John F McCarthy

John F. McCarthy, Sc.D., C.I.H.

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